

### **REMARKS/ARGUMENTS**

Claims 1-6 are pending in the application. Claims 1-6 have been amended, claims 7-18 have been added, and no claims have been canceled. Reconsideration of the present application in view of the following remarks, and a notice of allowance on all pending claims are respectfully requested.

Claim 1 has been amended to clarify that the invert soaps are utilized for disinfecting and cleaning a surface of confined lumina, such as for example, in an endoscope. This claim amendment is supported in the specification as filed, for example, at page 3, line 31 to page 4, line 1 of the translation of the specification. Claims 7-18 have been added to eliminate the multiple dependent format of claims 4-6 as previously presented.

### **Summary of the Invention**

The present invention, as defined by the claims, refers to the use of specific invert soaps that include at least one branched alkyl selected from nonyl, dodecyl, and tridecyl. Applicant has found that these specific invert soaps show a microbicidal effect, as well as a cleansing effect. The microbicidal effect of these compounds is such that they are effective against bacteria, fungi, and viruses and even against spores, all without an additional compound such as imidazoline or 2-bromo-2-nitropropane-1,3-diol. Additionally, these compounds have been found not to foam, which make them especially suitable for application to confined lumina, such as in endoscopes, as now claimed.

### **Rejections under 35 U.S.C. §§ 101 and 112, second paragraph**

Claim 1 stands rejected under 35 U.S.C. §101 "because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process . . ." (Office Action at 2). Claim 1 also stands rejected as indefinite under 35 U.S.C. §112, second paragraph, for failing to particularly point out and distinctly claim the subject matter that the Applicant regards as his invention. In this regard, the Office Action states that "[c]laim 1 provides for the use of invert soaps for disinfecting, but, since the claim

does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass" (*id.*).

Applicant has amended independent claim 1 to recite a method for disinfecting and cleaning surfaces of confined lumina that includes the step of contacting the confined lumina with an invert soap. Accordingly, Applicant respectfully requests that the pending rejections under 35 U.S.C. §§ 101 and 112, second paragraph, be withdrawn.

#### **Objection under 37 C.F.R. § 1.75(c)**

Claims 4-6 have been objected to under 37 C.F.R. § 1.75(c) "as being in improper form because a multiple dependent claim shall refer to another claim in the alternative only (claims 4 and 5) and because a multiple dependent claim shall not depend upon another multiple dependent claim (claim 6)" (Office Action at 3).

Applicant has amended claims 4-6 such that they are no longer in multiple dependent form. Accordingly, Applicant respectfully requests that this objection be withdrawn.

#### **Rejection under 35 U.S.C. § 102(b)**

The Examiner has rejected claims 1-6 under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 5,656,670 to Ajoku et al. ("Ajoku"). Applicant respectfully submits that Ajoku does not anticipate any of the claims of the present invention and, therefore, request that this rejection be withdrawn.

"It is by now well settled that the burden of establishing a prima facie case of anticipation resides with the Patent & Trademark Office." *In re Skinner*, 2 U.S.P.Q.2d 1788, 1788-89 (Bd. Pat. App. & Int. 1986). "If the examination at the initial stage does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent." *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992). "Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration." *W.L. Gore & Assocs. v. Garlock, Inc.*, 220 U.S.P.Q. 303, 313 (Fed. Cir. 1983). Applicant submits that Ajoku does not set forth each and every element of the invention defined by Applicant's claims.

The Office Action states that Ajoku "teaches the use of N-decyl-N-isonyl-N,N-dimethyl ammonium chloride, an invert soap, for disinfecting and cleaning surfaces and

devices" (Office Action at 3). Applicant respectfully disagrees with this rejection, but in the interest of facilitating prosecution, Applicant has amended independent claim 1 to now recite a method for disinfecting and cleaning a surface of "confined lumina" and can thus be clearly distinguished from the teachings of Ajoku. There is simply nothing in the cited art that teaches or suggests a method for disinfecting and cleaning a surface of confined lumina comprising contacting said confined lumina with an invert soap, wherein the invert soap contains at least one branched alkyl chain selected from nonyl, dodecyl and tridecyl, as instantly claimed. Accordingly, Applicant respectfully submits that the claims, as amended herein, clearly define over the art cited in the Office Action.

For the foregoing reasons, Applicant respectfully requests that the pending rejection under 35 U.S.C. § 102(b) be withdrawn.

**Rejection under 35 U.S.C. § 103(a)**

Claims 1-3 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,547,990 to Hall ("Hall").

The Office Action states that Hall "teaches the use of decylisononyldimethyl-ammonium chloride as a hard surface disinfectant cleaner" (Office Action at 4). The Office Action also states that "[a]lthough Hall et al does not expressly teach the treatment of devices, the disclosed use of the disinfectant/cleaner in household, industrial, and institutional environments would have lent it to be used on various devices and thus, such [a] use would have been obvious to one of ordinary skill in the art" (*id.*).

Applicant respectfully disagrees with the pending rejection as Hall discloses an anti-microbial composition comprising substituted imidazoline-based amphoteric and quaternary compounds, but does not mention any cleaning activity or the use of the invert soap alone for anti-microbial purpose. Nonetheless, in the interest of facilitating prosecution, Applicant has amended independent claim 1 to now recite a method for disinfecting and cleaning a surface of "confined lumina" and can thus be clearly distinguished from the teachings of Hall. Hall does not teach or suggest a method for disinfecting and cleaning a surface of confined lumina comprising contacting said confined lumina with an invert soap, wherein the invert soap contains at least one branched alkyl chain selected from nonyl, dodecyl and tridecyl, as instantly claimed.

Applicant respectfully submits that the claimed method, as presently amended, would not have been obvious to one of ordinary skill in the art viewing any of the cited prior art for a number of reasons. First, the specific invert soaps of the claimed method address the problem currently residing in the reduction of the processing time of medical devices, as well as reducing the risk of the personnel being contacted with disinfectants. It was surprisingly found that these invert soaps have not only cleansing effects, but due to the reduced trend of foaming, they can exert their microbicidal and cleansing effect in confined spaces of devices.

Second, Hall specifically *teaches away* from the Applicant's claimed invention in that the reference teaches that a combination of quaternary ammonium compounds *plus* imidazoline compounds produces superior microbicidal activity as compared to the quaternary compound alone (*see* col. 3, lines 1-3). In contrast, however, the claimed invention provides a method of cleansing and disinfecting confined lumina, such that no fixations or contaminations occur, with compounds that show excellent antimicrobial effects *without* the additional effects contributed by compounds such as imidazolines. Thus, Applicant respectfully submits that the cited art provides no teaching or suggestion of Applicant's claimed method and, in fact, the prior art teaches away from the claimed invention. Accordingly, Applicant respectfully submits that the claims, as amended herein, clearly define over the art cited in the Office Action.

For the foregoing reasons, Applicant respectfully requests that the pending rejection under 35 U.S.C. § 103(a) be withdrawn.

DOCKET NO.: BKS-0002  
Application No.: 09/913,629  
Office Action Dated: August 6, 2003

PATENT

### CONCLUSION

Applicant believes that the foregoing constitutes a complete and full response to the Office Action of record. Applicant respectfully requests allowance of claims 1-18.

Date: November 6, 2003



Steven D. Maslowski  
Registration No. 46,905

Woodcock Washburn LLP  
One Liberty Place - 46th Floor  
Philadelphia PA 19103  
Telephone: (215) 568-3100  
Facsimile: (215) 568-3439